COMMONWEALTH of VIRGINIA
Office of the Governor

Janet Vestal Kelly
Secretary of Health and Human Resources

TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable Mark D. Sickles
Chairman, House Committee on Health and Human Services

The Honorable Luke E. Torian
Chairman, House Committee on Appropriations

The Honorable Ghazala F. Hashmi
Chairman, Senate Committee on Education and Health

The Honorable Louise L. Lucas
Chairman, Senate Committee on Finance and Appropriations

FROM: The Honorable Janet Kelly
Secretary of Health and Human Resources

DATE: November 6, 2024

RE: Report on the Feasibility of a Wholesale Prescription Drug Importation Program in the Commonwealth

This report is submitted by the Secretary of the Health and Human Resources in compliance with Chapter 620 of the 2024 Acts of Assembly (SB186), which states:

> That the Secretary of Health and Human Resources (the Secretary) shall convene a work group composed of relevant stakeholders, including representatives from pharmaceutical manufacturers, health plans, and Virginia pharmacists, to (i) investigate wholesale prescription drug importation programs in other states, including the procedures for start-up and continued execution; (ii) evaluate best practices for the establishment and application of such a program; and (iii) consider the effectiveness of implementing such a program in the Commonwealth. The work group shall take into consideration the cost and safety of such a program. The Secretary shall provide a report on the feasibility of such a plan in the Commonwealth to the Governor, the Chairmen of the House Committees on Appropriations and Health and Human Services, and the Senate

Committees on Finance and Appropriations and Education and Health by November 1, 2024.

Should you have questions about this report, please feel free to contact Leah Mills, Deputy Secretary of Health and Human Resources at (804) 786-7765 or leah.mills@governor.virginia.gov.

Enclosure

cc: Arne Owens, Director, Department of Health Professions
Caroline D. Juran, RPh, Executive Director, Virginia Board of Pharmacy

Preface

This report is submitted in compliance with Chapter 620 of the 2024 Acts of Assembly, which states:

> That the Secretary of Health and Human Resources (the Secretary) shall convene a work group composed of relevant stakeholders, including representatives from pharmaceutical manufacturers, health plans, and Virginia pharmacists, to (i) investigate wholesale prescription drug importation programs in other states, including the procedures for start-up and continued execution; (ii) evaluate best practices for the establishment and application of such a program; and (iii) consider the effectiveness of implementing such a program in the Commonwealth. The work group shall take into consideration the cost and safety of such a program. The Secretary shall provide a report on the feasibility of such a plan in the Commonwealth to the Governor, the Chairmen of the House Committees on Appropriations and Health and Human Services, and the Senate Committees on Finance and Appropriations and Education and Health by November 1, 2024.

Contents

I. Executive Summary

The United States Food and Drug Administration ("FDA") has developed a pathway authorized under Section 804 of the Federal Food, Drug, and Cosmetic Act that allows importation of certain prescription drugs from Canada to significantly reduce the cost of these drugs to the American consumer without imposing additional risk to public health and safety. *See* 21 U.S.C. § 384. In October 2020, FDA issued a final rule[1] regarding the importation of prescription drugs, which describes the requirements for Section 804 Importation Program ("SIP") proposals and provides FDA responses to comments about the proposed rule. While several states have taken action to submit a SIP to the FDA, only Florida has received approval from the FDA, which was granted in January 2024. To date, no drugs have been imported from Canada under an FDA-approved SIP.

Pursuant to Chapter 620 of the 2024 Acts of Assembly, the Secretary of Health and Human Resources convened a work group of relevant stakeholders on September 20, 2024 to: (i) investigate wholesale prescription drug importation programs in other states, including the procedures for start-up and continued execution; (ii) evaluate best practices for the establishment and application of such a program; and (iii) consider the effectiveness of implementing such a program in the Commonwealth, while taking into consideration the cost and safety of such a program. A list of participants may be accessed in the draft minutes of the work group meeting. (*See* Attachment A.) The FDA provided a presentation regarding federal allowances for wholesale prescription drug importation programs. A representative of Florida's Agency for Health Care Administration provided information regarding Florida's FDA-approved SIP, and a consultant to Colorado's drug importation program provided information regarding Colorado's efforts to submit a SIP for FDA approval.

By consensus, the participants to the work group agreed that Virginia should monitor this subject and take no action until other states have proven that drugs can be successfully imported from Canada under the current federal structure for wholesale prescription drug importation.

Work Group Members

Leah Mills
Deputy Secretary of Health and Human Resources, Chair of the Work Group

Rebekah Allen
Chief Policy Advisor, Bureau of Insurance, Virginia State Corporation Commission

Nicole Wood
Pharmaceutical Research and Manufacturers of America

[1] 21 CFR Parts 1 and 251; *see* https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs.

Anne Leigh Kerr
Pharmaceutical Research and Manufacturers of America

Heidi Dix
Virginia Association of Health Plans

JoeMichael Fusco, PharmD
MCO Pharmacy Compliance Manager, Department of Medical Assistance Services

Jodi Roth
Virginia Retail Federation
Virginia Association of Chain Drug Stores

Nicara Neely, PharmD
Virginia Pharmacy Association

Joshua Crawford, PharmD
Virginia Society of Health-System Pharmacists

Stephanie Wheawill, PharmD
Director, Division of Pharmacy Services, Office of Epidemiology, Virginia Department of Health

Dr. Jessica Flanigan
Professor, University of Richmond

II. Wholesale Prescription Drug Importation Programs in Other States; Procedures for Start-Up and Continued Execution

The work group's discussion focused on the federal allowances for a state to submit a SIP to FDA for approval to import certain drugs from Canada and actions taken by Florida and Colorado to implement an importation program. However, other states' efforts were briefly acknowledged during the discussion. Per the National Conference of State Legislatures ("NCSL"), the following seven states have passed legislation to establish a state drug importation program: Colorado,[2] Florida,[3] Maine,[4] New Hampshire,[5] New Mexico,[6] Texas,[7] and Vermont.[8] Colorado, Florida, Maine, New Hampshire and New Mexico have submitted proposals to the FDA while Vermont submitted a concept letter to HHS and the Office of Management and Budget. Texas has not yet submitted a proposal. North Dakota[9] and Virginia[10] passed legislation establishing workgroups to examine the impact of a state importation program. Information regarding state legislation passed, status of SIP, population to be serviced, potential targeted drugs, projected savings, full time employee and appropriations is also accessible on NCSL's website.[11]

Florida

While Florida is the only state to receive approval from the FDA for a SIP proposal, its drug importation program has not been fully implemented. Florida's efforts toward implementing a state drug importation program began in 2018. State legislation was passed in 2019, and the initial SIP was submitted to FDA in 2020. Following four separate requests for information from the FDA and submissions of amended information, along with Florida-initiated litigation against the FDA for violation of the Administrative Procedure Act, FDA approval was received in January 2024. Florida must now submit a pre-import request to the FDA for approval. Florida's importation program is intended to service Medicaid patients, the Florida Department of Corrections, and other state-funded entities such as local health departments. Florida projects a savings of $183 million in Federal FY 2023-2024 and $196 million in 2024-2025. The state contracted with its actuary vendor, Milliman, to provide price and utilization projections, assumes 100% utilization for 14 drugs, and only includes savings from Florida Medicaid, not the other state agencies.

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[2] SB19-005 (Colo. 2019).
[3] Chapter No. 2019-99 (Fla. 2019).
[4] L.D. 1272 § 167 (129th Legis. 2019).
[5] House Bill 1280-FN (N.H. 2020).
[6] Senate Bill 1 (N.M. 2020).
[7] H.B. 25 (Tex. 2023).
[8] Act 133 (Ver. 2018).
[9] Senate Bill 2212 (N.D. 2021).
[10] Ch. 620 of the 2024 Acts of Assembly.
[11] *See* https://www.ncsl.org/health/state-drug-wholesale-importation-programs#:~:text=Five%20states%E2%80%94Colorado%2C%20Florida%2C,not%20yet%20submitted%20a%20proposal.

The SIP sponsor is the Agency for Health Care Administration which oversees Florida Medicaid and the co-sponsor is the Florida Department of Business and Professional Regulation, which regulates wholesale distributors. Florida's drug importation program has four staff members, receives annual appropriations, and pays its contracted importer a flat fee of approximately $14 million annually.

Challenges with implementation include identifying which drugs will yield cost-savings. Florida began with 130 drugs on its list and, after subsequent analyses, now has 14 drugs on its list with potentially four more drugs to be added. Florida had to compare where each state entity currently purchases drugs to perform cost analyses of each drug. Because generic drugs in Canada tend to cost more than in the United States, Florida focused on high-cost drugs for importation, such as specialty drugs. Federal regulations to require removal of any Canadian drug labels and affix FDA-approved drug labels without breaching the container, further limited drug eligibility.

Colorado

Unlike Florida, Colorado intends to service consumers in the commercial market. Colorado submitted an initial SIP to the FDA in March 2020. The first responsive request for information from FDA was received in March 2023. Colorado submitted its first amendment in February 2024 and its second in August 2024. The state is awaiting FDA approval or for a subsequent request for information. Colorado's drug importation program receives an annual appropriation of $2.1 million and includes 9 contract partners. Colorado estimates a savings of $50.9 million over the first three years.

Other state SIP submissions

- Maine submitted a SIP in 2020. Per NCSL, "[t]he Department of Health and Human Services would require significant funds to implement the program and costs unknown at this time."

- New Hampshire submitted a SIP in 2021. It was rejected by the FDA in 2022 because the state could not identify a Canadian wholesale distributor (foreign seller) to provide the drugs.

- New Mexico submitted a SIP in 2020 and is awaiting FDA approval.

III. Best Practices for the Establishment and Application of a Drug Importation Program

Florida recommended that states should consider the following questions when considering implementation of a state drug importation program:

- Who should receive the imported prescription drugs?
- Which functions should be delegated to vendors?
- Who should bear the risk of logistics and testing?
- What medications should be included?
- What is the proper number of personnel for implementation?

Best practices offered by Colorado include ensuring state legislation creates a flexible procurement process, fiscal support, and capacity for regulatory "teeth." Additionally, it recommends ensuring sufficient policy and supply chain expertise with the ability to perform due diligence of supply chain partners, keeping stakeholders informed, and being ready for resistance by some. Implementation challenges include needing the ability to negotiate to secure drug supply and resistance from drug manufacturers.

IV. Effectiveness of Implementing a Drug Importation Program in the Commonwealth, Considering Cost and Safety

Among the challenges discussed, the following were unclear to the work group:

- Whether a state drug importation program would yield cost-savings to the patient;
- If manufacturers will allow Canadian wholesale distributors to export their drugs to the United States or provide sufficient drug to Canada to offset exportation;
- If Canada will continue to oppose exportation of its drugs;
- If expanded access to drugs will disincentive pharmaceutical innovation leading to higher costs;
- If savings can be accurately projected since importation does not currently exist in the market;
- If the lowering of one drug's costs will result in another drug's increased cost;
- If the need to test and relabel drugs prior to importation can be reasonably performed; and
- If the length of time for FDA approvals will challenge a state's burden to implement an importation program.

By consensus,[12] the work group participants recommended that Virginia monitor this subject and take no action until other states have proven that drugs can be safely imported from Canada under the current federal structure for wholesale prescription drug importation and produce the intended cost-savings.

[12] Following the conclusion of the work group, the Healthcare Distribution Alliance ("HDA") provided comment that HDA members are concerned that wholesale importation programs could create supply chain problems in Virginia. HDA is the trade association for the nation's wholesale pharmaceutical distributors.

Attachment A

(DRAFT/UNAPPROVED)

VIRGINIA SECRETARY OF HEALTH AND HUMAN RESOURCES
MINUTES OF THE DRUG IMPORTATION WORK GROUP MEETING

September 20, 2024

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A meeting of a Drug Importation Work Group was called to order at 1:05PM.

PRESIDING: **Leah Mills**, Deputy Secretary of Health and Human Resources

PARTICIPANTS PRESENT IN-PERSON:

Rebekah Allen, Chief Policy Advisor, Bureau of Insurance, Virginia State Corporation Commission
Nicole Wood, Pharmaceutical Research and Manufacturers of America (left approximately 2:40pm, **Anne Leigh Kerr** took her place)
Heidi Dix, Virginia Association of Health Plans
JoeMichael Fusco, PharmD, MCO Pharmacy Compliance Manager, Pharmacy | Office of the Chief Medical Officer, Department of Medical Assistance Services
Jodi Roth, Government Affairs, Virginia Retail Federation, Virginia Association of Chain Drug Stores
Nicara Neely, PharmD, Virginia Pharmacy Association
Joshua Crawford, PharmD, Virginia Society of Health-System Pharmacists
Stephanie Wheawill, PharmD, Director, Division of Pharmacy Services, Office of Epidemiology, Virginia Department of Health (arrived approximately 1:50pm)
Dr. Jessica Flanigan, Professor, University of Richmond

PARTICIPANTS PRESENT VIRTUALLY:

Nai Chen, PharmD, CPh, Health Care Policy-Agency for Health Care Administration
Michelle Adams, MPH, Acting Director of Intergovernmental Affairs, Office of the Commissioner, U.S. Food and Drug Administration (FDA)
Chris Campbell, M.A., Senior Intergovernmental Affairs Specialist, OC, FDA
Leigh Verbois, PhD, Director, Office of Drug Security, Integrity, and Response (ODSIR), Center for Drug Evaluation and Research (CDER), FDA
Carole Jones, Director, Division of Global Drug Distribution and Policy (DGDDP), ODSIR, CDER, FDA
Andrei Perlloni, Branch Chief, Imports Compliance Branch (ICB), DGDDP, ODSIR, CDER, FDA

Paul George, Senior Regulatory Counsel, DGDDP, ODSIR, CDER, FDA
Mara Baer, Founder and President, AgoHealth LLC
Aaron Kearsley, Senior Economist at U.S. Department of Health and Human Services (HHS)
Karen Meister, Senior Policy Advisor, FDA
Jennifer Roe

STAFF PRESENT:

Arne Owens, Director, Virginia Department of Health Professions (DHP)
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP (left approximately 2pm, returned at 3:10pm)
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy

APPROVAL OF AGENDA:

Three handouts were provided to the in-person participants and public: a list of participants, comments from VACDS, and comments from Dr. Flanigan regarding the ethics and effectiveness of drug importation. The agenda was approved as presented.

PUBLIC COMMENTS:

No public comment was not offered.

REVIEW SB 186 AND OTHER BACKGROUND MATERIALS INCLUDED IN AGENDA

Leah Mills provided an overview of the work group's charge pursuant to SB 186 which required the Secretary of Health and Human Resources to convene a work group composed of relevant stakeholders, including representatives from pharmaceutical manufacturers, health plans, and Virginia pharmacists, to (i) investigate wholesale prescription drug importation programs in other states, including the procedures for start-up and continued execution; (ii) evaluate best practices for the establishment and application of such a program; and (iii) consider the effectiveness of implementing such a program in the Commonwealth. The bill further required the work group to take into consideration the cost and safety of such a program. The Secretary is to provide a report on the feasibility of such a plan in the Commonwealth to the Governor, the Chairmen of the House Committees on Appropriations and Health and Human Services, and the Senate Committees on Finance and Appropriations and Education and Health by November 1, 2024.

FEDERAL ALLOWANCE FOR IMPORTATION PATHWAY OF CERTAIN DRUGS FROM CANADA UNDER SECTION 804 OF THE FEDERAL FOOD,

Leigh Verbois, PhD, Director, ODSIR, CDER, FDA provided a PowerPoint presentation (Attachment 1) explaining the pathway authorized by the FDA that allows the importation of certain prescription drugs from Canada to significantly reduce the cost of drugs to American consumers without imposing any additional risks to public health and safety. An overview of the application process for drug importation proposals was provided. The

DRUG, AND COSMETIC ACT

presentation provided an overview of FDA regulations, the basic requirements of a Section 804 Importation Program (SIP) proposal, and the SIP proposal evaluation and decision process.

FLORIDA'S DRUG IMPORTATION PROGRAM

Nai Chen, PharmD, CPh, Healthcare Policy, Agency for Health Administration provided a PowerPoint presentation (Attachment 2) explaining Florida's Canadian Prescription Drug Importation Program. The presentation explained the federal requirements of the FDA and Florida's legislation regarding drug importation. While Florida is the only state to receive approval from the FDA for a SIP proposal, the drug importation program has not been fully implemented. Efforts toward this cause began in 2018, state legislation was passed in 2019, initial SIP was submitted in 2020, and FDA approval was received in January 2024. The importation process explaining the roles of the Canadian manufacturers, foreign sellers, importers, and state agencies was provided in detail. Dr. Chen provided a timeline of the implementation process utilized by Florida to receive their drug importation approval in January 2024. The cost savings of Florida's drug importation implementation was provided as well. Dr. Chen provided the following five questions to Virginia to consider during their journey of submitting a SIP proposal:

- Who should receive imported prescription drugs?
- Which functions should be delegated to vendors?
- Who should bear the risk of logistics and testing?
- What medications should be included?
- What is the proper number of personnel?

COLORADO'S DRUG IMPORATION PROGRAM

Mara Baer, Founder and President, AgoHealth LLC provided a PowerPoint presentation (pages 44-57 of agenda packet) regarding the implementation status of the Drug Importation Program in Colorado. The overview detailed Colorado Senate Bill 19-005 authorizing the submission of an importation application, annual appropriation, and expected savings of the program. A diagram displaying the contracts and program participants were provided. Ms. Baer provided a timeline of the implementation process utilized by Colorado as they are currently in the process of seeking approval from the FDA to allow drug importation from Canada. The presentation consisted of the best practices and procedures for start-up and ongoing SIP proposals. The presentation explained possible implementation challenges such as the need to negotiate to secure a drug supply, the resistance by drug manufacturers, and the lack of regulatory clarity. Ms. Baer explained the proposed cost savings and safety measures because of the implementation of Colorado's Drug Importation program.

DISCUSSION TOPICS TAKING INTO CONSIDERATION COST AND SAFETY

As required by SB 186, the work group reviewed and discussed the following factors to take into consideration of Virginia submitting a SIP proposal:

- What actions have other states taken to implement a drug importation program including their procedures for startup and continued execution?
- Evaluate the best practices for the establishment and application of such a program.
- Consider effectiveness of implementing such a program in Virginia

There was consensus that Virginia should continue to monitor this subject and take no further action at this time. The following comments were offered:

- Dix: She didn't hear of a benefit to the consumer. Medicaid already very complicated. Rebates and state plan exceptions would likely take years to resolve. Virginia may need to take a more nuanced approach than Florida.
- Flanigan: Expanded access to drugs may create general cost-savings but may disincentive pharmaceutical innovation leading to higher costs. Difficult to estimate savings since importation does not exist in the market. Lowering cost of one drug may be offset by an increased cost of another drug. US patent system is a problem. She has previously advocated for regulatory reciprocity wherein deference is given to another country's regulatory approval process.
- Roth: Aligns her comments with Dix's. Additionally, her members have concerns with drug safety associated with allowing importation.
- Crawford: Manufacturers not likely to participate. Why would a state go through testing vs. obtaining a cheaper contract?
- Fusco: Important to consider which population would be recipients. Is the vulnerable HIV positive population really the right group to test out this process?
- Wheawill: Most HIV medications currently purchased under 340B contracting. Concerned with access equity.
- Kerr: How do you ensure safety? How much would such a program cost Virginia? Florida has already spent at least $39 million dollars and no drugs have been imported. Canada continues to say they will not support exportation of its drugs for this purpose or ensure safety of drugs. Florida's population is equivalent to 2/3 of Canada's. Virginia should not proceed until we see if Canada will export drugs.
- Neely: Concerned with how long the SIP approval process has taken so far.
- Allen: Observed that Florida's legislation was very prescriptive, and Colorado has procurement flexibility that Virginia does not currently have. Procurement flexibilities must be considered and an acknowledgment that Florida's agencies are structured differently than Virginia's. The Florida agency primarily responsible for overseeing its program appears to be a combination of DMAS, VDH OLC, and VHI.

MEETING ADJOURNED: Having completed all business on the agenda, the meeting was adjourned at 4:15 PM.

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Caroline Juran,
Executive Director
Virginia Board of Pharmacy

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DATE: